March 2, 2015

Daniel E. O'Toole, Circuit Executive & Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: ***Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc., et al.,***
Nos. 2012-1567, -1568, -1569, -1570

Dear Admiral O'Toole:

Sandoz, Momenta, Mylan, and Natco submit this letter brief in response to the February 20, 2015 Order. On remand from the Supreme Court, this case presents a single issue—whether the new standard of appellate review for claim construction alters this Court's prior decision that the only claim of the sole remaining patent is invalid as indefinite. The answer is no.

Certainty and notice of patent boundaries are critical to an efficient patent system. Key to that notice is the public record created by the patentee—i.e., the claims, specification, and prosecution history. That public record must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). "'[T]he patent drafter is in the best position to resolve the ambiguity in . . . patent claims,'" and failure to do so renders the patent invalid. *Id.*

This Court previously reviewed the intrinsic record that Teva created to define the metes and bounds of its invention and correctly concluded, as a matter of law, that the patent claim now at issue is "insolubly ambiguous" under the prior test for indefiniteness. It is thus *a fortiori* indefinite under *Nautilus*'s lower standard. This Court recognized that a critical claim term—"molecular weight"—is concededly ambiguous on its face; that the prosecution history renders that ambiguity "insoluble" because Teva gave the PTO two irreconcilable answers as to the meaning of that term, each of which resulted in the issuance of a patent; and that the common

specification does nothing to resolve the ambiguity. 723 F.3d 1363, 1368-69 (Fed. Cir. 2013).

In the Supreme Court, Teva did not deny the existence of critical ambiguities in its patents and their prosecution history. Rather, Teva raised three narrow instances in which it contended this Court had rejected district court statements that were "facts." Only one such instance was actually a factual finding, and accepting that finding does nothing to eliminate the claims' ambiguity.

The other two challenged determinations were legal conclusions. As the United States told the Supreme Court, this Court's "analysis t[ook] issue with the legal inferences drawn by the district court rather than with that court's factual findings" and thus was "consistent with [a] requirement" to review factual findings for clear error. US S. Ct. Br. 26-27. In both instances challenged by Teva, this Court was reviewing district court conclusions regarding the understanding of a skilled artisan "*in the context of the patents-in-suit*." A306, A316 (emphasis added). As the Supreme Court made clear, how a skilled artisan would understand a claim term "*in the context of the specific patent claim under review*" is a legal question. 135 S. Ct. 831, 841 (2015) (emphasis by Supreme Court). This Court thus properly reviewed those district court statements de novo and correctly rejected them.

The prior judgment of indefiniteness should be reaffirmed—and as soon as practicable—because the sole remaining patent expires on September 1, 2015.

A. This Court Correctly Concluded That The Ambiguous Claim Language And Teva's Irreconcilable Statements To The PTO Render A Critical Claim Term Indefinite As A Matter of Law.

The "molecular weight" claims held indefinite by this Court cover copolymer-1 and methods of making it. 723 F.3d at 1367; *id.* at 1366 & n.2. These patents share a common specification and trace back to the same application. *Id.* at 1367; A289 & n.2. The sole claim of the '808 patent—the only unexpired patent—is representative, claiming a method of

manufacturing "copolymer-1 having a molecular weight of about 5 to 9 kilodaltons" (kDa). A346(col.6:5-11). This Court's indefiniteness decision turned on a critical ambiguity in the claim language that is rendered insoluble by plainly contradictory statements Teva made during prosecution of this family of patents—namely, that the same "molecular weight" term has two fundamentally different meanings. Because this Court rejected no factual findings in reaching that conclusion, the Supreme Court's decision does not change that result.[1]

1. "Molecular weight" has no single meaning. Starting with the claims themselves, this Court noted that it was "undisputed" that the "claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended." 723 F.3d at 1369.[2] As Teva conceded, there are several different ways to describe the molecular weight of copolymer-1, including weight average molecular weight (M_w), number average molecular weight (M_n), and peak molecular weight (M_p). *Id.* at 1367.

It also is undisputed that it is critical to know which type of molecular weight is intended to understand the limits of what is claimed because the same sample of copolymer-1 will have a *different molecular weight value* depending on whether M_w, M_n, or M_p is reported. *Id.* at 1367-68. Nevertheless, as the district court observed, "[t]he 'claims themselves' are silent as to the meaning," A305—even though it would have been simple for Teva to specify the type of molecular weight and even though, according to Teva, the effectiveness and reduced toxicity of

[1] Although Teva may try to invoke the clear-and-convincing evidence standard, that standard does not help it here because it does not apply to legal conclusions. *See Nautilus*, 134 S. Ct. at 2130 n.10 (suggesting that standard would be triggered only by "factual findings subsidiary to the ultimate issue of definiteness"). Nor does the "presumption of validity" aid Teva, because it "does not alter the degree of clarity that §112, ¶2 demands from patent applicants." *Id.*

[2] All parties agree that the terms "molecular weight" and "average molecular weight" in the claims at issue must have the same meaning, A1013-14 ¶¶55-57; the dispute is whether the claims fail to provide "clear notice" of *which type* of molecular weight is claimed. *See Nautilus*, 134 S. Ct. at 2129.

the claimed substance depend on its precise molecular weight, A18180, A18199.

This is not a situation where the district court found that "molecular weight" had "a particular meaning to a person of ordinary skill in the art at the time of the invention." 135 S. Ct. at 841. Quite the contrary: the district court determined (and all parties agreed) that the term "has no 'ordinary and customary meaning' in the context of copolymer-1." A305.

2. Teva's prosecution history statements render the ambiguity "insoluble." Faced with this concededly ambiguous claim term, this Court rejected Teva's effort to use the prosecution history to fill the gaps in its claims. 723 F.3d at 1369. During prosecution of this family of patents, the PTO reviewed the common specification and the proposed claims and, on two separate occasions, rejected Teva's claims for failure to specify the type of molecular weight: "The term 'average' molecular weight . . . is meaningless as a limitation without specifying its basis, e.g. weight average molecular weight, number average molecular weight, etc." A3220; *accord* A3245 ("the term 'average molecular weight' . . . is indefinite since its method of measurement is not specified"). Teva overcame these separate rejections by giving irreconcilable answers—once defining the term to mean "weight" average molecular weight and once defining it to mean "peak." 723 F.3d at 1369; A315; A3229; A3258.

This Court correctly held that, far from clarifying, Teva's irreconcilable answers to the PTO exacerbated the ambiguity in the claims. 723 F.3d at 1369. In so holding, this Court accepted the undisputed fact that Teva's *explanation* for one of its answers—"that kilodalton units implies [sic] a weight average molecular weight"—was "an evident scientific error." *Id.* at 1368.[3] But this Court correctly focused on Teva's two irreconcilable *answers*, each of which was material to patentability and resulted in issuance of a patent with the same specification and

[3] Teva incorrectly told the Supreme Court that this Court "never even acknowledged" this finding. Teva S. Ct. Br. 58.

the same claim term. *Id.* at 1369. As the Court explained: "[t]he only basis upon which the Examiner could have agreed that the '539 patent claims were not indefinite was that 'molecular weight' means M_p. In contrast, the only basis for the Examiner's withdrawal of the indefiniteness rejection of the '847 patent claims was that the same term means M_w." *Id.* The Court observed that "Teva's two definitions cannot be reconciled" and they thus "render[ed] the ambiguity insoluble." *Id.*

That analysis was purely legal—an interpretation of the patents and their prosecution history in light of the undisputed facts. Under the Supreme Court's decision, the meaning of "evidence intrinsic to the patent (the patent claims and specification[], along with the patent's prosecution history)" is "a determination of law." 135 S. Ct. at 841; *see In re Papst Licensing Digital Camera Patent Litig.*, __ F.3d __, 2015 WL 408127, at *3 (Fed. Cir. Feb. 2, 2015) (applying *Teva* and reviewing "the district court's claim constructions de novo, because intrinsic evidence fully determines the proper constructions").

This Court's conclusion was and is correct. Whatever Teva's rationale, the Examiner accepted Teva's answer that "*weight* average molecular weight" was the meaning of the otherwise ambiguous "molecular weight" claims and granted a patent because of that answer. *See, e.g.*, *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985) (noting that claims should be interpreted in light of applicant's responses to overcome rejections and gain allowance). The "scientific error" went only to Teva's *explanation* for its failure to specify the type of molecular weight, not to its *answer* about which measure the claims used. Because the precise type of "molecular weight" was key to these claims, neither the Examiner nor a skilled artisan would have reason to doubt that Teva knew which measure it intended, and no reason to doubt the "weight" part of Teva's answer. A skilled artisan would accept M_w as the

measure, even though Teva's excuse for not previously specifying it was scientifically inaccurate. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 996 (Fed. Cir. 2003) ("A reasonable competitor would have believed that the applicant's disclaiming statements were not a mere mistake."). But this response was just one of Teva's irreconcilable answers to the PTO, leaving a public record that confounds any effort to discern the meaning of the claims.[4]

3. The only purported "finding" of disputed fact is a legal conclusion. In the Supreme Court, Teva pointed to the district court's statement that, because Teva's explanation for its "weight" answer was scientifically "incorrect," "a person of ordinary skill in the art would not conclude that [average molecular weight], *in the context of the patents-in-suit*, 'implies . . . weight average molecular weight,'" but instead would rely on Teva's "peak" answer. A316 (emphasis added). Teva contended this analysis was a factual finding. Although the Supreme Court did not reach this contention, that statement was a legal conclusion entitled to no deference under its decision. It thus has no effect on the indefiniteness ruling.

As the Supreme Court made clear, the question of how a skilled artisan would understand

[4] In the Supreme Court, Teva argued for the first time that this prosecution history was irrelevant to the '808 patent, because both answers were made after that patent issued. Teva S. Ct. Br. 57. But all the patents—including the '808 patent—trace back to the same patent application, share the same specification, and contain the same "molecular weight" claim term. A person of ordinary skill in the art thus would look to the prosecution history of the entire family of patents to discern the scope of the claims. *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004); *see Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1312 (Fed. Cir. 2014). Indeed, while the other patents remained unexpired, Teva consistently argued that its "peak" answer (which Teva did not provide until after seven of the nine patents had issued) applied to *all* the claims in *all* the asserted patents, including the '808 claim. In this Court, Teva contended that "the prosecution history of one patent in a chain may be used to construe the same term in both earlier and later issued related patents with the same specification." Teva CAFC Br. 46 (citing *Microsoft*, 357 F.3d at 1350). In district court, Teva's expert repeatedly relied on the prosecution history answer of "peak" to give meaning to all the patents. *E.g.*, A1018 ¶65; A3096-97, SA3105, SA3121. Teva did so because, without that answer, there was nothing in the intrinsic record to support Teva's construction. If the inquiry now were limited to just the intrinsic record at the time of the '808 patent's issuance, that would simply confirm the claim's indefiniteness because there was *no* answer at that time as to which type of weight was intended.

a claim term "*in the context of the specific patent claim under review*" is a legal question, not a factual one. 135 S. Ct. at 841 (emphasis by Supreme Court). Only the district court's determination that Teva's explanation was scientifically inaccurate was factual. *See* US S. Ct. Br. 27-28. As the United States explained, the types of weight to which the "kilodalton" unit can refer "concern[ ] scientific principles and understandings as they exist in the field, outside the patent." *Id.* at 27. That scientific principle, however, has never been in dispute, and this Court's decision accepted that fact. 723 F.3d at 1368.

But the conclusion the district court drew from that uncontested principle to interpret the patent claims in light of their prosecution history was a legal one. 135 S. Ct. at 841. Indeed, in ruling that Teva's "weight" answer should be disregarded, the district court relied on a section of the declarations of Teva's expert, Dr. Grant, entitled "CLAIM CONSTRUCTION," which was based on his own interpretation of the patent record as a whole. A316 (citing A1017-18 ¶64); *see* A1017-18 ¶¶64-65.[5] Although the district court characterized its agreement with Grant's interpretation (A316 (relying on A1017-18 ¶64)) as a "finding," that label does not transform its legal conclusion into a factual finding. As the Supreme Court held, "'[e]xperts may be examined to explain terms of art, and the state of the art, at any given time,' but they cannot be used to prove 'the proper or legal construction of any instrument of writing.'" 135 S. Ct. at 841 (quoting *Winans*, 62 U.S. at 100-01). The "ultimate interpretive significance of representations in the prosecution history is a matter of law for the court to decide." US S. Ct. Br. 28.

In short, under the Supreme Court's decision, facts do not include a paid expert's interpretation of the public record at issue. The intrinsic record (which includes the prosecution history) is still reviewed de novo, and it remains paramount under *Phillips v. AWH Corp.*, 415

[5] The declarations stated: "In the paragraphs that follow, I set forth my opinion as to the proper interpretation of phrases or terms in the claims of the patents-in-suit." A7092 ¶54; SA1009 ¶44.

F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 135 S. Ct. at 840 ("[S]ubsidiary factfinding is unlikely to loom large in the universe of litigated claim construction."). For good reason: the notice function of patents would be severely undermined to the detriment of innovation and the patent system if the meaning of key terms could only be divined from expert litigation testimony.[6]

Thus, this Court correctly rejected, as a matter of law, Teva's attempt to use a litigation expert to negate a now-inconvenient answer to the PTO. Indeed, even if the import of Teva's explanation were viewed as a fact, a finding that discounted Teva's unambiguous answer would be clear error because Teva received a patent only by virtue of specifying M_w as the meaning of "molecular weight." *See Springs Window Fashions*, 323 F.3d at 996.

B. This Court's Legal Conclusion That "The Specification Does Not Resolve The Ambiguity" Is Unaffected By The Only Finding Of Disputed Fact Cited By Teva.

Turning to the specification, this Court correctly concluded that "[t]he specification does not resolve the ambiguity" created by the claims and the prosecution history. The new standard of review does not affect that conclusion.

1. This Court accepted the factual findings about SEC. This Court correctly

[6] In the Supreme Court, Teva contended a remand was warranted for this Court to consider the scientific error in light of its precedent regarding mistakes in prosecution. Teva S. Ct. Reply Br. 20-22 & n.10 (citing *Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1322 (Fed. Cir. 2001)). But this Court already did so, as the parties previously briefed this precedent. This Court's indefiniteness judgment reflects the correct conclusion that those decisions do not help Teva. Courts should not ignore an unequivocal answer like the one here, which contradicted neither the claims nor the specification, but rather purported to explain to the PTO the meaning of a key and otherwise undefined term—and was necessary to obtain a patent. *See Viskase*, 261 F.3d at 1322 (rejecting patentee's attempt to escape prosecution statement where alleged erroneous statement was "necessary to draw a line in this crowded field of technology"); *cf. Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1089-90 (Fed. Cir. 2003) (holding prosecution history statement "incorrect" because it "read[] into the claim two new limitations not required by the claim language"); *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1348 (Fed. Cir. 2001) (not enforcing statement that was inconsistent with the claims and the specification, "such that it would be unfair to enforce the error"). Nothing in the Supreme Court's decision alters the analysis, as all parties and this Court accepted the "evident" scientific error in Teva's explanation of its "weight" answer. 723 F.3d at 1368.

concluded that the specification's mere reference to the SEC method does not resolve the claims' ambiguity. 723 F.3d at 1369. As the United States explained, in reaching that conclusion, this Court "did not overturn or implicitly reject the district court's factual findings concerning SEC." US S. Ct. Br. 29. Although the Supreme Court did not reach this issue, the purported "fact" to which Teva seeks deference is actually a legal conclusion properly reviewed without deference. It thus has no effect on this Court's indefiniteness ruling.

The district court concluded that "Mp can be read from the chromatogram generated by SEC without any 'further calculation' and would be understood by a person of ordinary skill in the art to be the presumed meaning of [average molecular weight] *in the context of the patents-in-suit*." A306 (citing A1016 ¶61) (emphasis added); *see* A312. In the Supreme Court, Teva contended that statement was a finding of "fact." But only the first part of the district court's statement—that "Mp can be read from the chromatogram generated by SEC without any 'further calculation'"—is factual. US S. Ct. Br. 29-30.

The district court found that the data generated by the SEC method are plotted on a graph, called a chromatogram. A306 (citing SA1007-08 ¶41). By running "standards" of known molecular weight through the same SEC column, a calibration curve can be created. SA1008-09 ¶42. M_p "'can be obtained directly from the chromatogram and the calibration curve,'" A307 (citing A1016 ¶61), without any 'further calculation.'" A306 (citing A1016 ¶61). Sandoz and Mylan did not dispute these scientific principles. Indeed, there was no dispute as to the various types of weight the SEC method can measure in general. As the district court recognized, SEC "can also provide Mw and Mn" if further calculations are performed. A312.[7]

[7] Although Teva pointed the Supreme Court to Grant's statement that "[i]t is uncommon . . . for only one of M_n or M_w to be listed when referencing data generated by SEC," Teva S. Ct. Br. 57, the district court made no such finding, as Fed. R. Civ. P. 52(a)(1) would require.

As the Supreme Court made clear, a district court's conclusion about what a method of measurement means "*in the context of the patents-in-suit*," A306 (emphasis added), is a legal one. 135 S. Ct. at 841. That principle is dispositive here. As the United States explained, "[t]he district court concluded that Dr. Grant's testimony concerning the data that SEC can generate, *combined with* the absence of any reference in the patent to the additional calculations that would be needed to determine M_n or M_w, indicates that 'molecular weight' in the claims means M_p." US S. Ct. Br. 31 (emphasis in original). "But determinations concerning the appropriate inferences to be drawn from other portions of the patent itself are legal rather than factual." *Id.*

The district court's determination was again simply an endorsement of Grant's "Claim Construction" analysis, based on Grant's reading of the intrinsic record. A1016 ¶61. Indeed, Grant expressly did *not* assert that "peak molecular weight" was the "default meaning to a person of skill in the art." A3096-97. Grant pointed instead to the prosecution history. A3097. Although the district court purported to "credit" Grant's interpretation, A312 (citing A7097-98 ¶70), "[t]hat conclusion, though phrased as a credibility finding, is a legal determination," US S. Ct. Br. 30. The district court simply determined, as a matter of law, what it believed to be "the presumed meaning of [average molecular weight] *in the context of the patents-in-suit*." A306 (emphasis added). As the Supreme Court emphasized in both *Markman* and this case, "*in the actual interpretation of the patent the court proceeds upon its own responsibility, as an arbiter of the law*." 135 S. Ct. at 841 (internal quotation marks omitted).

This Court disagreed only with the district court's legal conclusion. The Court accepted that M_p can be "read directly from a plot of SEC data," whereas "some calculations" are required to obtain M_n and M_w. 723 F.3d at 1369. But it emphasized that "SEC does not exclusively provide M_p—both M_n and M_w can also be obtained from the data generated by the SEC method."

Id. Given those undisputed scientific principles, this Court concluded as a matter of law that the mere reference to SEC did not establish that the claims mean "peak." *Id.*

That conclusion was and is correct. *See Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1340-41 (Fed. Cir. 2003) (claim indefinite where patent failed to specify which of four methods was intended for critical term). As *Nautilus* teaches, "there is an indefiniteness problem if the claim language 'might mean several different things and "no informed and confident choice is available among the contending definitions."'" *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (quoting *Nautilus*, 134 S. Ct. at 2130 & n.8). Here, the specification contains no mention of the intended measure, even though it would have been simple to include. The fact that, with a chromatogram and a "proper calibration curve" in place, the peak molecular weight "can be read directly off the calibration curve," SA1008-09 ¶¶42-43, does not establish the claims refer to peak. The specification contains no calibration curve. A344-46. Nor does it suggest that further calculations would not be needed. A344-46. The parties agreed that the relevant skill in the art was very high, SA7070-71 ¶21, and that all three types of average molecular weight could be obtained using the SEC method, A1005 ¶39; A1229 ¶37; SA7081 ¶39. Moreover, the Examiner reviewed the specification and twice rejected the claims for indefiniteness despite the reference to SEC; neither time did the applicants rely on the reference to SEC to overcome the indefiniteness rejection. A3229; A3258. Indeed, even if the Court were to review the district court's legal conclusion as a factual finding, it would be clearly erroneous.

2. The fact of a slight shift in Figure 1 does not eliminate the ambiguity. The only actual finding of disputed fact that Teva has identified cannot cure the ambiguities in the patent and its prosecution history. The Supreme Court held that the district court's determination that a skilled artisan would expect the curves in a figure like Figure 1 to shift slightly upon creation

was a factual finding. But as the United States suggested, that finding does not alter this Court's "ultimate conclusion that the claim of the '808 patent is indefinite." US S. Ct. Br. 32-33 (noting "it appears likely that the Federal Circuit will ultimately reaffirm its conclusion that the patent is indefinite"). At most, the finding suggests that Figure 1 does not *exclude* the possibility that the claims could be interpreted to refer to peak molecular weight. That does nothing to eliminate—and only serves to confirm—the claims' ambiguity.

It is undisputed that the points along the horizontal axis where Figure 1's three curves peak do not match the values for average molecular weight in the Figure's legend. A342. For the two overlapping curves identified by the legend as having an average molecular weight of 7.7 kDa, Grant "measured the peak to be at 6.8 kDa." A1017 ¶62. For those same curves, Grant calculated the "weight" average molecular weight to be 8.3 to 8.5 kDa. A5825. The district court found that a skilled artisan would understand that the process of creating molecular weight distribution curves (such as in Figure 1) from data generated by an SEC chromatogram "'would likely cause the peak on each curve to shift slightly'" from where it was on the chromatogram. A308 (quoting A1016-17 ¶62); *see* A7085-92 ¶¶44-53 (explaining shift). The Supreme Court held this was a factual finding that must be accepted unless clearly erroneous. 135 S. Ct. at 843.

The Supreme Court further held, however, that the conclusion the district court made based on that finding was a legal one, *id.*, even though the district court had purported to "credit" and "accept" Grant's self-described "Claim Construction," A313 (citing A1016-17 ¶62). Specifically, the district court concluded that "the fact that the peaks in Figure 1 do not match the listed [average molecular weights] precisely would not dissuade a person of ordinary skill in the art from concluding that [average molecular weight] refers to Mp in the context of the patents-in-suit." A313 (citing A1016-17 ¶62). The district court relied on Grant's declaration, in which he

used his own calculation of the peaks in the Figure's curves to opine that "[t]he peaks of the curves are close to those numbers [in the Figure's legend], which would support the assumption that the numbers in the legend were peak molecular weights." A1016 ¶62.

To be sure, this Court did not expressly accept the factual finding subsequently identified by the Supreme Court. 723 F.3d at 1369. But it did not reject the finding, and this Court's legal conclusion is fully consistent with it. Without questioning the fact that a skilled artisan would expect a slight shift in the curves, this Court relied on Teva's *own* expert's calculations and opinions to conclude that Figure 1 could not resolve the facial ambiguity of Teva's claims.[8]

Grant's interpretation hinged on the peaks at 6.8 kDa in the overlapping curves being "close" enough to the "corresponding" 7.7 kDa in the legend to be within an unspecified "margin of error" due to the expected slight shift. SA7098-99 ¶72. In other words, Grant stated that the peaks in the curves could represent M_p because he expected each peak to "shift slightly" due to the transformation of the data from the chromatogram. SA7098 ¶72. Grant explained that the magnitude of the expected shift in such a graph, and whether it would shift right or left, would depend on the underlying data. A7086-87 ¶46, A7092 ¶53. But Grant conceded that he could not determine the shift's *magnitude* or *direction* in Figure 1 because he did not have, and did not ask Teva for, the underlying "primary data" (which were not in the public record). A3107-08.

That Grant, a person highly skilled in the art, could not know the shift's direction or magnitude without access to data not provided in the intrinsic record should alone be enough to conclude that Figure 1 provides no reasonable certainty about the meaning of "molecular

[8] Teva told the Supreme Court that this Court "simply eyeballed its way to its own decision accepting the view of Mylan's expert instead of Teva's." Teva S. Ct. Br. 55. Not so: this Court did not even mention the testimony from Mylan's expert that he would expect no shift in the curves, and neither Sandoz nor Mylan relied on it in this Court. Nor did this Court or the district court rely on Mylan's expert's calculation of M_w in Figure 1. *Cf. id.* at 56 n.34.

weight." But even under his reasoning, the fact of a shift does not establish the claims mean M_p.

Given that Grant was willing to read the peaks at 6.8 kDa as showing the M_p of the batches corresponding to the 7.7 kDa values in the legend, his expected margin of error was a shift in the overlapping curves of at least 0.9 kDa in either direction. Yet Grant's own calculation of the M_w of those curves was likewise within that same margin of error; indeed, as this Court noted, Grant's M_w calculation was "closer" to the legend's 7.7 kDa value. 723 F.3d at 1369 (citing A5[82]5). Grant calculated the M_w of those curves to be 8.3 to 8.5 kDa (A5825)—a 0.6 to 0.8 difference from the 7.7 kDa values in the legend. Accordingly, *either* measure, M_w or M_p, is fully consistent with the expected slight shift in the curves, and the ambiguity remains.

What Figure 1 suggests (if anything) about the meaning of "molecular weight" "in the context of the specific patent claim under review" is a legal conclusion. 135 S. Ct. at 841 (emphasis omitted). That is clear from the Supreme Court's decision, which expressly held that the district court's determination "that figure 1 did not undermine Teva's argument that molecular weight referred to . . . peak" was a "legal conclusion." *Id.* at 843 (citing A313). Given that neither type of measure (as calculated by *Teva's* expert) matched the legend, but both were close to the legend's values, this Court correctly concluded that this "makes it difficult to conclude [from Figure 1] that M_p is the intended measure." 723 F.3d at 1369 (citing A5[82]5).

In any event, as the United States explained to the Supreme Court, "Figure 1's failure to illustrate M_p values" was merely "an *additional* reason" this Court held the patents indefinite. US S. Ct. Br. 33. Contrary to Teva's assertion in the Supreme Court, this Court did not "th[ink] that because the peak of Figure 1 does not fall at 7.7 kDa, Figure 1 essentially rules out Teva's interpretation (peak average)." Teva S. Ct. Reply 20 (emphasis omitted). Rather, this Court simply held it does not *establish* that the claims refer to peak. 723 F.3d at 1369. Indeed, even

the district court ultimately concluded only that Figure 1 "would not *dissuade* a person of ordinary skill in the art from concluding" that the "molecular weight" term refers to "peak molecular weight." A313 (emphasis added). "Would not dissuade" falls far short of "compels" or even "implies." It is a neutral conclusion that leaves open all possible interpretations.

In sum, accepting the fact of a slight curve shift does not establish that "molecular weight" means peak. At most, it simply does not exclude the possibility. Indeed, any contrary conclusion would not only be legal error, it would be clearly erroneous.[9]

C. A Ruling Reaffirming Invalidity Is Urgently Needed.

Given the short time left on the '808 patent, this Court's indefiniteness judgment should be swiftly reaffirmed, with an opinion to follow as necessary. If Teva's last patent expires before then, Teva will have maintained its monopoly over Copaxone® based on patents this Court previously held invalid.[10] While Sandoz and Mylan may market upon FDA approval under threat of infringement liability, they should not face that risk any longer than necessary.

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[9] Teva itself has now acknowledged under oath that claim 1 of the '808 patent "is invalid under 35 U.S.C. 112, second paragraph, for indefiniteness," in the course of asking the PTO to reissue the patent. Appl. No. 13/964,856, http://portal.uspto.gov/pair/PublicPair (search by application number); *see* Amendment to Reissue Application Declaration, *In re Reissue Application of U.S. Patent No. 5,800,808*, Appl. No. 13/964,856 (Feb. 13, 2014). The PTO rejected the reissue application, and Teva continues to pursue reissue on appeal in the PTO.

[10] A decision is all the more urgent because of Teva's ongoing efforts to undercut the present Copaxone® market before the introduction of generic alternatives. Copaxone® has traditionally been administered in daily 20-mg injections—the version of the drug at issue here. But in January 2014, Teva obtained FDA approval for a version of the drug that is administered in 40-mg injections. The 40-mg version purportedly is covered by separate patents that, if valid, will not expire until 2030. *See* http://www.accessdata.fda.gov/scripts/Cder/ob/docs/obdetail.cfm?Appl_No=020622&TABLE1=OB_Rx (last visited Feb. 27, 2015). Teva is moving the Copaxone® market to that version because "the more patients it converts ahead of generic approvals, the higher the probability insurers won't force those customers to switch back to daily shots once generics become available." David Wainer, *Teva's Early Copaxone Conversion Effort Convincing Analysts*, Wash. Post, Mar. 11, 2014.

Dated: March 2, 2015

Respectfully submitted,

/s/ Shannon M. Bloodworth
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Counsel for Defendants-Appellants Sandoz Inc. and Momenta Pharmaceuticals, Inc.

cc: All Counsel (by ECF)

CERTIFICATES OF INTEREST

Counsel for defendants-appellants Sandoz Inc. and Momenta Pharmaceuticals, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Sandoz Inc.
Momenta Pharmaceuticals, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc.: Sandoz Inc. is an indirect subsidiary of Novartis AG. Novartis AG's shares are listed and traded on the SIX Swiss Exchange as well as on the NYSE in the form of American Depositary Receipts representing Novartis American Depositary Shares.

Momenta Pharmaceuticals, Inc.: None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

Morrison & Foerster LLP: Anders T. Aannestad, Eric M. Acker, Matthew Mark D'Amore, David C. Doyle, Adam A. Eltoukhy (no longer with firm), Grant J. Esposito, Karen L. Hagberg, Marc A. Hearron, Stephen D. Keane, Brian M. Kramer, Brian R. Matsui, Deanne E. Maynard, Richard B. Mills-Robertson (no longer with firm)

Dated: March 2, 2015 /s/ Deanne E. Maynard

Counsel for defendants-appellants Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd. certifies the following:

1. The full name of every party or amicus represented by me is: Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd.

2. The parties named in the caption that I represent are the real parties in interest.

3. Defendant Mylan Inc. states that it is a publicly held corporation and that no parent corporation or publicly held corporation owns more than 10 percent of its stock.

4. Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc. There are no other parent corporations or publicly held companies that own more than a 10 percent interest in Mylan Pharmaceuticals Inc.

5. Natco Pharma Ltd. states that it is a publicly held corporation and that no parent corporation or publicly held corporation owns more than 10 percent of its stock.

6. The names of the law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

PERKINS COIE LLP: Shannon M. Bloodworth, Brandon M. White, Sarah C. Walkenhorst, David L. Anstaett, John S. Skilton, Melody K. Glazer, David E. Jones, Colin G. Sandercock, Alfonso N. Cornish, Eric D. Miller.

SIDLEY AUSTIN LLP: Carter G. Phillips, Ryan C. Morris, Jeffrey P. Kushan, Adam Hallowell, Steven J. Horowitz.

FRIEDMAN KAPLAN SEILER & ADELMAN LLP: Andrew Levine, Ricardo Solano Jr. and Kenneth N. Ebie.

SCHIFF HARDIN LLP: Beth D. Jacob.

CRAVATH, SWAINE & MOORE LLP: Evan R. Chesler, Richard J. Stark.

Dated: March 2, 2015 /s/ Shannon M. Bloodworth

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on March 2, 2015.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: March 2, 2015 /s/ Deanne E. Maynard